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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/011,860	11/05/2001	Gust H. Bardy	032580.0042.CIP	6000

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EXAMINER	
MULLEN, KRISTEN DROESCH	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/011,860	BARDY ET AL.	
	Examiner	Art Unit	
	Kristen Mullen	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2004 (RESPONSE)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *6/3/04* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-8, 12-13, 15-24, 28-29, 31-40, 44-45, 47-56, 60-61, and 63-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Kroll (5,978,703).

Regarding claims 1, 17, and 33, Kroll shows an ICD comprising a housing (140) having an electrically conductive surface area of an outer surface of the housing (Fig. 2b), a lead assembly electrically coupled to the housing and having an electrode, a power supply or voltage output system comprising a capacitor subsystem (22, 24, 26) and a battery subsystem (12) electrically coupled to the capacitor subsystem, wherein the energy comprises a monophasic waveform having a peak voltage that is between approximately 25 V and approximately 50 V. (Fig. 4; Col. Col. 4, line 42- Col. 5, line 18).

With respect to claims 5, 21, and 37, Kroll shows an ICD comprising a housing (140) having an electrically conductive surface area of an outer surface of the housing (Fig. 2b), a lead assembly electrically coupled to the housing and having an electrode, a power supply or voltage output system comprising a capacitor subsystem (22, 24, 26) and a battery subsystem (12) electrically coupled to the capacitor subsystem, wherein the energy comprises a monophasic waveform having a peak voltage that is between approximately 50V and approximately 75 V. (Fig. 4; Col. Col. 4, line 42- Col. 5, line 18).

Regarding claims 6, 22, and 38, Kroll shows an ICD comprising a housing (140) having an electrically conductive surface area of an outer surface of the housing (Fig. 2b), a lead assembly electrically coupled to the housing and having an electrode, a power supply or voltage output system comprising a capacitor subsystem (22, 24, 26) and a battery subsystem (12) electrically coupled to the capacitor subsystem, wherein the energy comprises a monophasic waveform having a peak voltage that is between approximately 75 V and approximately 100 V. (Fig. 4; Col. Co1. 4, line 42- Col. 5, line 18).

With respect to claims 7-8, 23-24, and 39-40, Kroll shows an ICD comprising a housing (140) having an electrically conductive surface area of an outer surface of the housing (Fig. 2b), a lead assembly electrically coupled to the housing and having an electrode, a power supply or voltage output system comprising a capacitor subsystem (22, 24, 26) and a battery subsystem (12) electrically coupled to the capacitor subsystem, wherein the energy comprises a monophasic waveform having a pulse width that is between approximately 1 ms and approximately 40 ms, or between approximately 1 ms and approximately 10 ms (Fig. 4; Col. 4, line 42- Col. 5, line 18).

Regarding claim 49, Kroll shows a method comprising generating energy, storing the energy, delivering the energy to the patient's heart; wherein the energy comprises a monophasic waveform having a peak voltage that is between approximately 25 V and approximately 50 V. (Fig. 4; Col. Col. 4, line 42- Col. 5, line 18).

With respect to claims 53, Kroll shows a method comprising generating energy, storing the energy', delivering the energy to the patient's heart; wherein the energy comprises a monophasic waveform having a peak voltage that is between approximately 50V and approximately 75 V. (Fig. 4; Col. Col. 4, line 42- Col. 5, line 18).

Regarding claim 54, Kroll shows a method comprising generating energy, storing the energy; delivering the energy to the patient's heart; wherein the energy comprises a monophasic waveform having a peak voltage that is between approximately 75 V and approximately 100 V. (Fig. 4; Col. Col. 4, line 42- Col. 5, line 18).

With respect to claims 55-56, Kroll shows a method comprising generating energy, storing the energy; delivering the energy to the patient's heart; wherein the energy comprises a monophasic waveform having a pulse width that is between approximately 1 ms and approximately 40 ms, or between approximately 2 ms and approximately 10 ms (Fig. 4; Col. Col. 4, line 42- Col. 5, line 18).

With respect to claims 2-4, 18-20, 34-36, and 50-52, Kroll shows the energy comprises a monophasic waveform having a peak voltage that is between approximately 0.1 Volts and approximately 100 Volts, or between approximately 0.1 Volts and approximately 25 Volts, or between approximately 25 Volts and approximately 50 Volts, (Fig. 4., Col. Col. 4, line 42- Col. 5, line 18).

With respect to claims 12-13, 28-29, 44-45, and 60-61, Kroll shows the energy comprises a monophasic waveform (41) including a positive waveform with a tilt between approximately 5% to approximately 95% (Fig. 4).

Regarding claims 15-16, 31-32, 47-48, and 63-64 Kroll shows the energy comprises a monophasic waveform that is provided at a rate of between approximately 20 to approximately 120 stimuli/minute and is provided in response to asystole (rate less than 20 beats/min) (Fig. 4; Abs; Col. Col. 4, line 42- Col. 5, line 18).

The statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

With respect to claims 65-69, the statements regarding the subcutaneous positioning of the ICD between the third and fifth ribs, fourth and sixth ribs, sixth and eighth ribs, eighth and tenth ribs and tenth and twelfth ribs have not been considered since the statements only modify the introductory statement of intended use. The Kroll ICD could be positioned in any of these locations if desired.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 9-11, 14, 25-27, 30, 41-43, 46, 57-59, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll (5,978,703).

With respect to claims 9-11, 25-27, 41-43, and 57-59, Kroll discloses the claimed invention except for the monophasic waveform having a pulse width between approximately 10 milliseconds and approximately 20 milliseconds, between approximately 20 milliseconds and approximately 30 milliseconds, and between approximately 30 milliseconds and approximately 40 milliseconds. It would have been an obvious design choice to one with ordinary skill in the alï at the time the invention was made to modify the monophasic waveform pulse width as taught by Kroll with monophasic waveforms having a pulse width between approximately 10 milliseconds and approximately 20 milliseconds, between approximately 20 milliseconds and approximately

30 milliseconds, and between approximately 30 milliseconds and approximately 40 milliseconds, since applicant has not disclosed that these particular monophasic waveform pulse widths provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any monophasic waveform pulse width such as between approximately 1 millisecond as taught by Kroll for applying pacing pulses.

Regarding claims 14, 30, 46, and 62 Kroll discloses the claimed invention except for the monophasic waveform having a tilt of 50%. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the tilt of the monophasic waveform as taught by Kroll with a 50% tilt, since applicant has not disclosed that this particular tilt provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any tilt such as the 5% to 90% tilt taught by Kroll for applying pacing pulses.

Response to Arguments

5. Applicant's arguments filed 12/17/04 have been fully considered but they are not persuasive. The term "anti-bradycardia pacing" is a statement of intended use. The device of Kroll is fully capable of functioning as an anti-bradycardia pacing device since it meets the structural limitations of the claim. The Kroll device has a capacitor subsystem, a battery subsystem coupled to the capacitor subsystem which provides energy to the capacitor subsystem and stores energy that has a monophasic waveform with a peak voltage and pulse width with the claimed ranges. The fact that the device of Kroll is not used for this purpose according to the disclosure is irrelevant.

Furthermore, Kroll teaches peak voltages and pulse widths that are within, overlapping or touching the claimed ranges. This is all that is necessary for anticipation of a range. See MPEP § 2131.06

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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